

CLAIMS

1. Dietetic, nutrient or pharmaceutical composition, characterized in that it comprises alkaline sphingomyelinase in an amount that is sufficient to  
5 exert a dietetic, nutritional or therapeutic effect in an individual who need it.
2. Composition according to Claim 1, suitable for the prevention and/or treatment of disorders connected with intestinal development, cancerous processes, disorders  
10 of the immune response, inflammatory and apoptotic processes of the intestine and its associated structures, disorders connected with cholesterol synthesis, disorders due to the hydrophobic nature of the surfaces of the gastrointestinal tract, allergic  
15 disorders of the gastro-intestinal tract, disorders relating to digestive processes, inflammatory intestinal diseases, polyposis, in particular familial polyposis, hypercholesterolaemia, infections with *Helicobacter pylori*, disorders of neonatal growth,  
20 disorders connected with intestinal homeostasis and diseases of the central and peripheral nervous systems.
3. Composition according to Claim 1 or 2, suitable for use in pediatric diets.
4. Composition according to Claim 1 or 2, suitable  
25 for use in enteral alimentation.
5. Composition according to Claim 3, characterized in that the composition is administered, in combination with artificial milk, condensed milk, soybean milk,

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powdered milk, partially umanized milk and baby foods in general.

6. Composition according to any one of the preceding claims, characterized in that the alkaline sphingomyelinase is of bacterial origin, and the bacteria containing the alkaline sphingomyelinase are chosen from amongst Gram-positive bacteria, Gram-negative bacteria and lactic acid bacteria, or from mixtures thereof.

7. Composition according to Claim 6, characterized in that the lactic acid bacteria are chosen from the group comprising *Lactobacillus acidophilus*, *Lactobacillus brevis*, *Lactobacillus buchneri*, *Lactobacillus casei*, *Lactobacillus cateniformis*, *Lactobacillus cellobiosus*, *Lactobacillus crispatus*, *Lactobacillus curvatus*, *Lactobacillus delbrueckii*, *Lactobacillus fermentum*, *Lactobacillus jensenii*, *Lactobacillus leichmannii*, *Lactobacillus minutus*, *Lactobacillus plantarum*, *Lactobacillus rogosae*, *Lactobacillus salivarius*, *Bifidobacterium adolescentis*, *Bifidobacterium angulatum*, *Bifidobacterium bifidum*, *Bifidobacterium breve*, *Bifidobacterium catenulatum*, *Bifidobacterium dentium*, *Bifidobacterium eriksonii*, *Bifidobacterium infantis*, *Bifidobacterium longum*, *Bifidobacterium plantarum*, *Bifidobacterium pseudocatenulatum*, *Bifidobacterium pseudolongum*, *Streptococcus lactis*, *Streptococcus raffinolactis* and *Streptococcus thermophilus*.

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8. Composition according to Claim 7, characterized in that the *Lactobacillus brevis* CD2 strain is used, which is filed on February 6, 1998 under access No. DSM 11,988 in the German Collection of Microorganisms and Cell Cultures (DSM) in Braunschweig, Germany ("Deutsche Sammlung von Mikroorganismen und Zellkulturen GmbH"), or mutants or derivatives thereof under the Budapest Treaty.

9. Composition according to anyone of the preceding claims, characterized in that the lactic acid bacteria are used in the composition as live, lyophilized or sonicated bacteria.

10. Composition according to any one of the preceding claims, characterized in that it contains from  $1 \times 10^2$  to  $1 \times 10^{13}$  CFUs of lactic acid bacteria per gram of composition.

11. Composition according to any one of Claims 7 to 9, characterized in that it contains  $200 \times 10^9$  *Streptococcus thermophilus*,  $150 \times 10^9$  Bifidobacteria and  $4 \times 10^9$  *Lactobacillus acidophilus* per gram of composition.

12. Composition according to any one of the preceding claims, characterized in that it also contains bile acids, in particular ursodeoxycholic acid, pectin, sphingomyelin or its compounds, drugs or foods containing sphingomyelin, arginine deiminase, fatty acids, polyunsaturated fatty acids, non fermented sugars, in particular lactulose, cholesterol.

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inhibitors, ceramidase inhibitors, protease inhibitors, immunomodulators, anti-carcinogenic agents, vitamins, growth factors, surfactants, cereals, fibre, emulsifiers, stabilizers, lipids, antioxidants, preservatives, free-radical neutralizers and/or vaso-protectors.

13. Composition according to any one of the preceding claims, which can be administered orally as a food supplement.

14. Composition according to any one of the preceding claims, which can be administered orally or parenterally as a drug.

15. Use of alkaline sphingomyelinase for the preparation of a dietetic, nutrient or pharmaceutical composition suitable for the prevention and/or treatment of disorders connected with intestinal development, cancerous processes, disorders of the immune response, inflammatory and apoptotic processes of the intestine and its associated structures, disorders connected with cholesterol synthesis, disorders due to the hydrophobic nature of the surfaces of the gastrointestinal tract, allergic disorders of the gastro-intestinal tract, disorders relating to digestive processes, inflammatory intestinal diseases, polyposis, in particular familial polyposis, hypercholesterolaemia, infections with *Helicobacter pylori*, disorders of neonatal growth, disorders

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connected with intestinal homeostasis and diseases of the central and peripheral nervous systems.

16. Use according to Claim 15 in pediatric diets.

17. Use according to Claim 15, in enteral

5 alimentation.

18. Use according to Claim 16, characterized in that the composition is administered, in combination with artificial milk, condensed milk, soybean milk, powdered milk, partially unanized milk and baby foods in

10 general.

19. Use according to any one of Claims 15 to 18, in which the alkaline sphingomyelinase is of bacterial origin, and the bacteria containing it are chosen from amongst Gram-positive bacteria, Gram-negative bacteria and lactic acid bacteria, or from mixtures thereof.

20. Use according to Claim 19, characterized in that the lactic acid bacteria are chosen from the group comprising *Lactobacillus acidophilus*, *Lactobacillus brevis*, *Lactobacillus buchneri*, *Lactobacillus casei*,  
20 *Lactobacillus cateniformis*, *Lactobacillus cellobiosus*, *Lactobacillus crispatus*, *Lactobacillus curvatus*, *Lactobacillus delbrueckii*, *Lactobacillus fermentum*, *Lactobacillus jensenii*, *Lactobacillus leichmannii*, *Lactobacillus minutus*, *Lactobacillus plantarum*,  
25 *Lactobacillus rogosae*, *Lactobacillus salivarius*, *Bifidobacterium adolescentis*, *Bifidobacterium angulatum*, *Bifidobacterium bifidum*, *Bifidobacterium breve*, *Bifidobacterium catenulatum*, *Bifidobacterium*

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dentium, *Bifidobacterium eriksonii*, *Bifidobacterium infantis*, *Bifidobacterium longum*, *Bifidobacterium plantarum*, *Bifidobacterium pseudocatenulatum*, *Bifidobacterium pseudolongum*, *Streptococcus lactis*,  
5 *Streptococcus raffinolactis* and *Streptococcus thermophilus*.

21. Use according to Claim 20, characterized in that the *Lactobacillus brevis* CD2 strain is used, which is filed on February 6, 1998 under access No. DSM 11,988  
10 in the German Collection of Microorganisms and Cell Cultures (DSM) in Braunschweig, Germany ("Deutsche Sammlung von Mikroorganismen und Zellkulturen GmbH") under the Budapest Treaty, or mutants or derivatives thereof.

15 22. Use according to any one of Claims 15 to 21, characterized in that the lactic acid bacteria are used in the composition as live, lyophilized or sonicated bacteria.

23. Use according to any one of Claims 15 to 21,  
20 characterized in that from  $1 \times 10^2$  to  $1 \times 10^{13}$  CFUs of lactic acid bacteria are used per gram of composition.

24. Use according to any one of Claims 15 to 21, characterized in that  $200 \times 10^9$  *Streptococcus thermophilus*,  $150 \times 10^9$  *Bifidobacteria* and  $4 \times 10^9$   
25 *Lactobacillus acidophilus* are used per gram of composition.

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